UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/624,530 | 07/24/2000 | Richard Sackler | 200.93185C2C | 5659 |

23280 7590 10/04/2004

DAVIDSON, DAVIDSON & KAPPEL, LLC
485 SEVENTH AVENUE, 14TH FLOOR
NEW YORK, NY 10018

| EXAMINER | |
|---|---|
| MITCHELL, GREGORY W | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1617 | |

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/624,530 | SACKLER ET AL. | |
| | Examiner | Art Unit | |
| | Gregory W Mitchell | 1617 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *03 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *6-10,13-16 and 20-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-10,13-16 and 20-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

This office action is in response to the remarks and amendments filed by Applicant on June 3, 2004. Claims 6-10, 13-16 and 20-23 are pending and are examined herein.

Applicant's amendment to claim 13 has remedied the vague and indefinite problem and the 35 U.S.C. 112(2) rejection therefor is hereby withdrawn.

### *Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 3, 2004 has been entered.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6-7, 9 and 13-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Paradissis et al. (USPN 5133974).

Paradissis et al. Discloses extended release pharmaceutical formulations. A 24 hour time period is disclosed as the extended release. The formulation comprises a mixture of 0-50% of an immediate release particle containing a drug, substrate and binder, coated with talc, and up to 100% of an extended release particle that coats the immediate release particle with a dissolution modifying system containing plasticizers and a film forming agent. Narcotics, such as morphine, are disclosed as drugs. The drug adheres to an inert spherical substrate particle through a binding agent, which is applied by a solvent. It is exemplified that inert spherical substrate particle are placed in a suitable coating pan to which the drug is added and the binder solution is then sprayed onto the mixture. Hydroxypropylmethyl cellulose, hydroxypropyl cellulose, ethyl cellulose, acrylic acid copolymers and methacrylic acid copolymers are disclosed as binders. Water insoluble hydrophobic plasticizers disclosed include castor oil, propylene glycol and mixtures thereof. Ethyl cellulose, methyl cellulose, acrylic and methacrylic acid copolymers are disclosed as film forming polymers. See col. 4, line26-col.8, line 26; claim 22.

Thus, the instant claimed invention encompasses and Paradissis discloses extended release drug formulations comprising a drug coated with matrix spheroids that are coated with an acrylic copolymer or ethylcellulose and comprise hydroxylower alkylcellulose or acrylic polymer, which is further coated with a controlled release matrix comprising alkylcellulose or cellulose ether and a hydrocarbon and polyalkylene glycol.

The examiner respectfully points out that a compound and its properties are inseparable. *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA1963). Thus, the extended release pharmaceutical formulation of Paradissis et al. must exhibit the same properties as that recited in the instant claims.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 8, 10 and 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paradissis et al. as applied to claims 6-7, 9 and 11-16.

The instant invention is directed toward a method for treating pain in humans for a time period of about 24 hours, comprising preparing a solid, controlled-release oral dosage form, the dosage form comprising an analgesically effective amount of an opoid analgesic, wherein the analgesic is contained in a controlled-release matrix.

Paradissis et al. Is applied as disclosed above. Furthermore, morphine, hydromorphone, and oxycodone are taught as interchangeable narcotics for use in the invention. Amounts of at least 50 mg per dosage form are disclosed. See col. 4, lines 26-59; col. 5, lines 13-23. The reference lacks an exemplification of hydromorphone, oxycodone, and dosage amounts.

It would have been obvious to one of ordinary skill in the art to substitute morphine with either oxycodone or hydromorphone because (1) Paradissis et al. teaches that the derivatives of morphine and codeine are useful in the instant invention; and (2) Paradissis et al. teaches that oxycodone and hydromorphone are derivatives of morphine and codeine. One would have been motivated to use such a formulation because of an expectation of success in achieving pain relief equivalent to that achieved by using a morphine formulation.

It would have been obvious to one of ordinary skill at the time of the invention to exemplify the formulations of Paradissis et al. as comprising at least 50 mg of drug because of the expectation of achieving dosage amounts that are effective to treat different levels and forms of pain, and different weight amounts of patients. Furthermore, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

***Response to Arguments***

Applicant's arguments filed June 3, 2004 have been fully considered but they are not persuasive. Applicant argues that the invention of the instant applicant is distinct from that of Paradissis et al. because "the claims of the present invention recite that the opoid is dispersed in a controlled-release matrix, whereas in the dosage form described in the Paradissis reference, the drug is applied to an inert core and coated with a dissolution modifying system to provide for controlled release." Applicant's argument is

not persuasive because Applicant's claims are directed to an "opioid analgesic being contained in a controlled-release matrix," not to an opioid "dispersed in a controlled-release matrix." The plain language interpretation of "contained" clearly includes a composition wherein the opioid is contained completely within a matrix coating.

Applicant also argues that the terminology "matrix," itself, means that the "opioid analgesic is interdispersed in a material which provides for the controlled release of the opioid." Applicant provides a "Pharmacy Review" reference that indicates that "the most common method of preparation [of a matrix] is mixing of the drug with the matrix material followed by compression of the material into tablets." This argument is not convincing. As the reference states, it is the "most common method," not that it is the only method. Accordingly, the reference does not indicate that a coated material cannot be defined as a matrix. Indeed, Webster's Third New International Dictionary (1986, 1393, 2a) defines a matrix as "something (as a **surrounding** or pervading substance or element) within which something else originates or takes form or develops." Therefore, the plain meaning and the broadest reasonable interpretation of a matrix would include a matrix material that *surrounds* the opioid analgesic.

Accordingly, the 35 U.S.C. 102 and 103 rejections are deemed proper because it is Examiner's position that the broadest reasonable interpretation of a matrix encompasses the coated bead formulation of Paradissis et al.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory W Mitchell whose telephone number is 571-272-2907. The examiner can normally be reached on M-F, 8 AM - 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

gwm

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER